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10/586,649

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EXAMINER

OJURONGBE, OLATUNDE S

ART UNIT

PAPER NUMBER

1796

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/586,649	<b>Applicant(s)</b> SEIFALIAN ET AL.	
	<b>Examiner</b> OLATUNDE S. OJURONGBE	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 38-76 is/are pending in the application.
- 4a) Of the above claim(s) 50-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-49 and 58-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20070108; 20060719</u> .                                      | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group (i), claims 38-49 and 58-76 in the reply filed on 02/09/2009 is acknowledged. Claims 50-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention.

### ***Claim Objections***

2. Claims 65, 66 and 68 are objected to because of the following informalities:

Claim 65 recites "A process for producing a copolymer according to claim 39, which process comprises.....(i) one or more pendant group segments, the or each segment being bonded ". The underlined parts make the statements grammatically wrong.

Claim 66 recites "A process for producing a copolymer according to claim 39, ....which process comprises (i).." The underlined part makes the statement grammatically wrong.

Claim 68 recites "A process for producing a lined copolymer, which process comprises".

The underlined part makes the statement grammatically wrong.

Appropriate corrections are required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 38-49 and 58-76** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites "[P]<sub>n'</sub>-[Lys]<sub>n</sub> is a dendritic structure formed from n lysine groups and terminating in n' groups P; n' is zero or an integer of up to 16". It is unclear how n' can be zero when P]<sub>n'</sub>-[Lys]<sub>n</sub> terminates in n' groups P.

Dependent claims 39-49, 53 and 58-76 are rejected for the same reason.

Claims 67 and 69 recite "A copolymer/ lined copolymer obtained or obtainable". It is unclear whether the copolymer/lined copolymer is obtainable by different processes or not, and what the different processes are in case that the copolymer/lined copolymer is obtainable by different processes.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 38-43, 47-48, 59-60, 63, 65 and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by **Hanada et al (EP 0324946)**.

Regarding **claims 38-40**, Hanada et al teaches a polyurethane resin containing as pendants, residual groups of the siloxane compound of formula (1) and/or formula (2); said polyurethane is obtained by reacting components that include polyol and polyisocyanate (page 4, lines 27-31).

Regarding **claims 41-42**, the residual groups of the siloxane compound of formula (1) and/or formula (2) of Hanada et al meet the claim limitations.

Regarding **claims 74 and 43**, the residual groups of the siloxane compound of formula (1) and/or formula (2) of Hanada et al meet the claim limitations. Starting from the first  $R_3\text{-Si}$  unto the last  $\text{OCH}_2$  unit of the residual groups serve as S, a linear siloxane group and the residual units of  $R'\text{C}(\text{CH}_2\text{OH})_2$  and/or  $\text{CH}(\text{OH})\text{CH}_3$  of formula (1) and/or formula (2) serve as Y of the instant claim respectively.

Regarding **claims 47 and 48**, Hanada et al further exemplifies a composition obtained from 4 parts of polydimethylsiloxanepolyol with a molecular weight of 4,500 and 146 parts of polybutylene adipate (see Example 3, page 8, lines 1-22). The polyurethane formed from the exemplified amounts of polydimethylsiloxanepolyol and polybutylene adipate has a ratio of siloxane segment(s) to polyol segment(s) within the claimed range.

Regarding **claims 59-60**, Hanada et al further teaches the polyurethane of the invention containing a chain extender (page 4, lines 30-31) and exemplifies the chain extenders of the invention to include 1,4-butanediol (page 5, lines 14-30 and see Example 3, page 8, lines 1-22). The segment of the polyurethane of Hanada et al formed from the exemplified 1,4-butanediol is a  $\text{C}_4$  aliphatic moiety.

Regarding **claim 63**, Hanada et al further exemplifies the composition of Example 3.

The polyurethane- wherein the segments of the polyurethane are linked by the diisocyanate residue-formed from the composition of Example 3 meets the limitation of the instant claim.

Regarding **claim 65**, Hanada et al teaches a polyurethane resin containing as pendants, residual groups of the siloxane compound of formula (1) and/or formula (2); said polyurethane is obtained by reacting components that include polyol and polyisocyanate (page 4, lines 27-31). Hanada et al further exemplifies reacting polydimethylsiloxane polyol, polybutylene adipate, 1,4-butanediol and hydrogenated MDI to obtain a polyurethane (see Example 3, page 8, lines 5-25).

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 38- 48,59-60,63,65,67-68,70-71,73** are rejected under 35 U.S.C. 102(e) as being anticipated by **Sahatjian et al (US 2005/0010275)**.

Regarding **claims 38-40**, Sahatjian et al teaches polyurethanes made by reacting (A) a polyol, (B) a dihydroxyl-terminated POSS and (C) a diisocyanate [0085]. Sahatjian et al further teaches the dihydroxyl-terminated POSS of the invention to include the

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structures of [0086] and [0087] and exemplifies the polyurethane with the structure of [0131]. The polyurethane, the POSS and the polyol of Sahatjian et al, exemplified in the structure of [0131] serve as the copolymer, the one or more pendant group segment and the one or more polyol segments of the instant claim respectively.

Regarding **claims 41-42**, the  $\text{-O-Si(CH}_3)_2\text{-}$  unit of the pendant POSS of the exemplified structure of [0131] of Sahatjian et al meets the claim limitations.

Regarding **claims 47 and 76**, Sahatjian et al further teaches that the X/Y for the structure of [0131] is for example 1 to 20.

Regarding **claims 74, 43-46**, the polyurethane of Sahatjian et al formed from the POSS structure of [0086] meets the claim limitations wherein the caged structure serves as S and starting from the first  $\text{CH}_2$ , unto the cyclohexane serves as the aliphatic group Y of the instant claim.

Regarding **claim 48**, the exemplified POSS of structure [0131] meets the claim limitations.

Regarding **claims 59**, the exemplified structure [0131] meets the claim limitations; the diisocyanate residue serves as the one or more chain extender segments of the instant claim.

Regarding **claim 60**, Sahatjian et al further teaches the diisocyanates (C) of the invention to include hexamethylene-1,6-diisocyanate [0085]. The polyurethane of Sahatjian et al formed from hexamethylene-1,6-diisocyanate meets the claim limitation; the hexamethylene-1,6-diisocyanate residue serves as the chain extender, wherein said chain extender segment is C<sub>1</sub>-C<sub>6</sub> aliphatic moiety.

Regarding **claim 63**, the exemplified structure [0131] meets the claim limitations. The segments of the polyurethane are linked by the diisocyanate residue; the diisocyanate residue meets the claim limitations.

Regarding **claims 65 and 67**, Sahatjian et al teaches polyurethanes made by reacting (A) a polyol, (B) a dihydroxyl-terminated POSS and (C) a diisocyanate [0085]. Sahatjian et al further exemplifies the polyurethane with the structure of [0131].

Regarding **claims 70-71**, Sahatjian et al further teaches implantable medical devices, for example, a stent including the polymer of the invention [0007 and 0079-0085].

Regarding **claim 68**, Sahatjian et al teaches polyurethanes made by reacting (A) a polyol, (B) a dihydroxyl-terminated POSS and (C) a diisocyanate [0085]. Sahatjian et al further exemplifies the polyurethane with the structure of [0131]. Sahatjian et al further teaches that the use of the polymer of the invention-including the polyurethane-in



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implantable medical devices, for example, a stent [0007] and further teaches inserting the stent of the invention in for example, a prostatic urethra [0113].

By teaching the insertion of the stent containing the polyurethane of the invention in a prostatic urethra, Sahatjian et al inherently teaches a process of producing a lined copolymer of the instant claim because the cells of the prostatic urethra are introduced (seeded) onto the surface of the stent containing the polyurethane, hence, the polyurethane of the invention. The seeded polyurethane serves as the lined copolymer of the instant claim.

Regarding **claim 73**, Sahatjian et al teaches replacing various passageways, such as arteries, with a medical endoprosthesis, examples of which include stents. [0002]. Sahatjian et al further teaches the stent of the invention including the polymer of the invention [0007].

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 49, and 58-59** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sahatjian et al (US 2005/0010275)**.

Regarding **claims 49 and 58**, Sahatjian et al teaches all the claim limitations as set forth above. Though Sahatjian et al does not teach a copolymer which comprises two or more different pendant siloxane segments/pendant group segments of the instant claim, since Sahatjian et al teaches examples of the POSS of the invention to include the structures of [0086] and [0087], one of ordinary skill in the art would have used a combination of the POSS of structure [0086] and structure [0087] as the POSS of the invention by routine experimentation with an expectation of success. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the

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very same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. [*In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)].

The polyurethane formed from such combination meets the instant claim limitations.

Regarding **claim 59**, Sahatjian et al teaches all the claim limitations as set forth above. Though Sahatjian et al does not teach a copolymer further comprising (c) one or more chain extender segments of the instant claim, since Sahatjian et al teaches examples of the POSS of the invention to include the structures of [0086] and [0087], one of ordinary skill in the art would have used a combination of the POSS of structure [0086] and structure [0087] as the POSS of the invention by routine experimentation with an expectation of success. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. [*In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)].

The polyurethane formed from such combination meets the instant claim limitations, wherein the structure of [0086] serves as the chain extender segment.

Regarding **claim 75**, Sahatjian et al teaches all the claim limitations as set forth above.

Sahatjian et al further teaches that the polyurethane copolymers of the invention may be

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bioabsorbable and exemplifies the structure wherein X/Y is from 1 to 20 and the degree of polymerization, m, is from 2 to 100 [0131].

Though Sahatjian et al does not teach the copolymer according to claim 74, wherein the pendant arm is attached at the end of the copolymer chain, the examiner notes that some of the polyurethane copolymers-such as the polyurethane copolymers wherein X/Y is 1 and m is 2-of Sahatjian et al meet the claim limitations, hence render the claim unpatentable over Sahatjian et al.

11. **Claims 64** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Sahatjian et al (US 2005/0010275)** in view of **Pinchuk (US 4,739,013)**.

Regarding **claim 64**, Sahatjian et al teaches all the claim limitations as set forth above.

Though Sahatjian et al does not teach the copolymer which comprises as component (b) one or more polycarbonate segment(s) of the instant claim, Sahatjian et al further teaches examples of the polyol of the invention to include polycaprolactone [0085].

Pinchuk teaches polyurethanes formed by reacting -OH or hydroxyl group of a macroglycol component with an -NCO or isocyanate group of a diisocyanate and silanol terminated siloxane (col.3, lines 5-12 and col.4, lines 41-55).

Pinchuk further teaches the macroglycols of the invention to include polycarbonate and polyester, such as polycaprolactone or polyacrylate (col.3, lines 45-51).

Since polycarbonate and polyester, such as polycaprolactone, are known equivalents in the art- as taught by Pinchuk-motivated by the desire to generate polyurethanes with optimal properties, it would have been obvious to one of ordinary skill in the art to have

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incorporated one or more polycarbonate of Pinchuk into the composition of Sahatjian et al.

12. **Claims 38 and 70-72** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Pinchuk (US 4,739,013)** in view of **Sahatjian et al (US 2005/0010275)**.

Pinchuk teaches polyurethanes formed by reacting -OH or hydroxyl group of a macroglycol component with an -NCO or isocyanate group of a diisocyanate and silanol terminated siloxane (col.3, lines 5-12 and col.4, lines 41-55).

Pinchuk further teaches that the polyurethane materials of the invention are suitable for vascular grafts (col.2, lines 3-10).

Pinchuk does not teach the copolymer of the instant claim 38 and/or the molded article and/or the implantable device of the instant claim.

Sahatjian et al teaches polyurethanes made by reacting (A) a polyol, (B) a dihydroxyl-terminated POSS and (C) a diisocyanate [0085]. Sahatjian et al further teaches the dihydroxyl-terminated POSS of the invention to include the structures of [0086] and [0087] and exemplifies the polyurethane with the structure of [0131]. Sahatjian et al further teaches that the polymer of the invention has a melt or glass transition temperature above body temperature and exhibits an approximate plateau in a plot of storage modulus as a function of temperature at melt or glass transition [0013].

Since both compositions of the invention of Sahatjian et al and Pinchuk are similar, motivated by the melt or glass transition temperature of the polymer of Sahatjian et al, it would have been obvious to one of ordinary skill in the art to have formed the

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vascular graft of Pinchuk utilizing any of the polymer, including the polyurethane, of Sahatjian et al.

### **International Search Report (ISR)**

13. The International Search Report (ISR) has been considered and the above references are the closest to the present invention.

### ***Allowable Subject Matter***

14. Claim 66 is allowable over prior art because there is no reference that suggests the process of the claim.

### ***Conclusion***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLATUNDE S. OJURONGBE whose telephone number is (571)270-3876. The examiner can normally be reached on Monday-Thursday, 7.15am-4.45pm, EST time, Alt Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571)272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

O.S.O.

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